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PTO/SB/01 (03-01)

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

Declaration
Submitted
with Initial
Filing

Number(s)

OR

Declaration
Submitted after Initial
Filing (surcharge
(37 CFR 1.16 (e))
required)

Attorney Docket Number		FSTK 1004-1US
First Named Inventor		MICHAEL G. KAHN
COMPL	ETE IF	KNOWN
Application Number	09	/ 974,781
Filing Date	OC	TOBER 10, 2001
Group Art Unit	216	6
Examiner Name	UNI	KNOWN

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY

1000	(Title of	the Invention)				
the specification of which						
is attached hereto						
OR was filed on (MM/DD/YYYY)	10/10/20	01 as United S	tates Application	Number or PCT In	ternational	
Application Number 09/97	4,781 and was	amended on (MM/DD/YY	YY)		(if applicable).	
I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.						
I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.						
I hereby claim foreign priority benoor plant breeder's rights certificate than the United States of Americ patent, inventor's or plant breeder application on which priority is claim	e(s), or 365(a) of any F a, listed below and ha 's rights certificate(s), o	PCT international applica ve also identified below,	tion which desig bv checking the	nated at least one box, any foreign	country other application for	
Prior Foreign Application	_	Foreign Filing Date	Priority	Certified Cop	y Attached?	

[Page 1 of 2]

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

(MM/DD/YYYY)

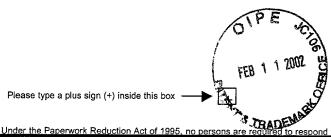
Not Claimed

Country

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to:	Customer Numbe or Bar Code Labe	- 1 22,7	70	OR Co	orrespondence address below
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City		W. W. L.	State	3	ZIP
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Country	Tele	ephone			Fax
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.					
NAME OF SOLE OR FIRST INVENTOR: A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])	MICHAEL	G.		ily Name urname	KAHN
Inventor's Signature Michaelle Inc. 2001					
BOUL	DER	CC)	USA	USA
Residence: City		State		Country	Citizenship
3980 GREEN Mailing Address	BRIAR BC			Country	Citizensinp
BOULDER	D	CC	$\overline{}$	80303	USA
DOULDER City	X	State	' 1	1 1	
		- L			Country
NAME OF SECOND INVENTOR	<u>(: </u>	A petition nas	been	n filed for this unsig	ned inventor
Given Name CARO (first and middle [if any])	L A.		Family or Surr	y Name BROVEI rname	RMAN
Inventor's Signature					
			$\overline{}$		Date
MENLO Residence: City	[CA State	1	USA ountry	USA Citizenship
303 CONCO	RD DRIVE	;	_		
MENLO PAR		CA State	ZIF	94025	USA
Additional inventors are being name	- 1				SB/02A attached hereto.
Additional inventors are being name	on thesupp	hemeniai Additioi.	al lrive	intor(s) sneed(s) PTO/O	3B/02A attached nereto.



PTO/SB/02A (11-00)
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DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet Page _ 1_ of _1_

Name of Additional Joint Inventor, if			□ Ар€	etition has been fi	led for	this unsigned inventor
Given Name (first and middle [if ar	ıy])			Family Nar	me or §	Surname
KELLY A.				K	ING	DON
Inventor's Signature						Date
Residence: City SAN RAFAEL	State	CA	Countr	USA		USA Citizenship
4 MOUNT DIABLE	O CIRCI	_E 				-
Mailing Address	···					
city SAN RAFAEL	State	CA	ZIP	94903	Countr	ry USA
Name of Additional Joint Inventor, if a	ıny:		☐ A petif	tion has been filer	d for thi	is unsigned inventor
Given Name (first and middle [if an	<u>y])</u>			Family Nam	ne or S	Surname
Inventor's Signature	***					Date
Residence: City	State		Countr	ry		Citizenship
Mailing Address				-		· · · · · · · · · · · · · · · · · · ·
Mailing Address						
City	State		ZIP		Cour	•
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Name of Additional Joint Inventor, if a] A petitio	in has been filed f	for this	unsigned inventor
Given Name (first and middle [if any	1)	_	Family Name or Surname			
Inventor's Signature			1			Date
Residence: City	State		Countr	:ry	<u></u>	Citizenship
Mailing Address						
Mailing Address						
City	State		ZIP		Cor	untrv

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DECLARATION FOR UPILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

Declaration
Submitted
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OR

Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number		FSTK 1004-1US			
First Named Inventor		MICHAEL G. KAHN			
COMPL	ETE IF	KNOWN			
Application Number	09	974,781			
Filing Date	OC'	TOBER 10, 2001			
Group Art Unit	216	5			
Examiner Name	UNK	NOWN			

As a below named inventor, I hereby declare that:

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CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY

	(Title of	the Invention)				
the specification of which is attached hereto						
OR was filed on (MM/DD/YYYY)	10/10/20	as United S	States Application	Number or PCT In	nternational	
Application Number $09/974,781$ and was amended on (MM/DD/YYYY) (if applicable).						
I hereby state that I have reviewed amended by any amendment spe	d and understand the co cifically referred to abov	ontents of the above iden e.	tified specification	n, including the cla	ıims, as	
I acknowledge the duty to disclose in-part applications, material inforr PCT international filing date of the	nanon wolco became av	vallanie netween the tilin	defined in 37 CF g date of the prior	R 1.56, including f r application and th	or continuation- ne national or	
I hereby claim foreign priority ben or plant breeder's rights certificate than the United States of Americ patent, inventor's or plant breeder application on which priority is claim	e(s), or 355(a) of any F a, listed below and hav 's rights certificate(s), c	CI international application also identified below	ation which desig	inated at least one	e country other	
Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Cop YES	by Attached?	

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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DECLARATION — Utility or Design Patent Application

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Direct all correspondence to: Customer or Bar Co		22,1	70 —	OR C	Correspondence a	address below
Name						
Address			1			
City			State		ZIP	
Country I hereby declare that all statements made herein of		phone	'ma ar	1 II = 4 = II eletements	Fax	" and holiof
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.						
	NAME OF SOLE OR FIRST INVENTOR: A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any]) KAHN Family Name or Surname				1		
Inventor's Signature					Date	
BOULDER		CO	,	USA		USA
Residence: City		State		Country	Citizenship	
3980 GREENBRIAF	₹ BOt	ULEVARD	,			
Mailing Address ROLLINED	— Т			90202		TTOA
BOULDER city		CO	- 1	80303	Country	USA
NAME OF SECOND INVENTOR:				filed for this unsig		
Given Name CAROL A.		F	amily N	Name BROVE		
nventor's X (MC A. Bra		1 5	or Surna	ame	Date X Jan	8 2002
MENLO PARK Residence: City	St	CA	Cour	USA	Citizenship	USA
303 CONCORD DR	IVE					
MENLO PARK	St	CA tate	ZIP	94025	Country	USA
$m{Z}$ Additional inventors are being named on the $_1$	supple	emental Additiona	I Invent	tor(s) sheet(s) PTO/S	B/02A attached	hereto.



Please type a plus sign (+) inside this box -

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DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet Page _1 of _1_

Name of Additional Joint Inventor, if any: A petition has been filed for this unsigned inventor						this unsigned inventor	
Given Name (first and middle [if a	ny])		Family Name or Surname				
KELLY A.						DON	
Inventor's Signature						Date	
Residence: City SAN RAFAEL	Stat	CA te	Countr	USA y_		USA Citizenship	
Mailing Address 4 MOUNT DIABL	O CII	RCLE					
Mailing Address			 -				
city SAN RAFAEL	Stat	e CA	ZIP	94903	Count	USA	
Name of Additional Joint Inventor, if any:					is unsigned inventor		
Given Name (first and middle [if any])			Family Name or Surname				
Inventor's Signature						Date	
Residence: City	Stat	e	Country	1		Citizenship	
Mailing Address							
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City	Stat	e	ZIP		Cour	ntry	
Name of Additional Joint Inventor, if a	iny:		A petition	has been filed	for this	unsigned inventor	
Given Name (first and middle [if any	<u>(1)</u>		Family Name or Surname				
Inventor's Signature						Date	
Residence: City	State		Country	<u>, </u>		Citizenship	
Mailing Address							
Mailing Address							
City	State		ZIP		Cou	intry	

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Declaration Submitted with Initial Filing

Declaration Submitted after Initial Filing (surcharge (37 ČFR 1.16 (e)) required)

Attorney Docket Number		FSTK 1004-1US
First Named Inventor		MICHAEL G. KAHN
COMPLETE IF		KNOWN
Application Number	09	974,781
Filing Date	OC'	ГОВЕR 10, 2001
Group Art Unit	216	6
Examiner Name	UNF	KNOWN

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CLIMICAL TRIAL RROTTOCOL OLLALITY

USING A MODEL-BASED METHODOLOGY					
L	(Title of	the Invention)			
the specification of which	·	·			
is attached hereto					
OR was filed on (MM/DD/YYYY)	10/10/20	as United S	tates Application	Number or PCT International	
Application Number 09/97	44,781 and was	amended on (MM/DD/YY	YY)	(if applicable).	
I hereby state that I have reviewed amended by any amendment spe			tified specification	i, including the claims, as	
I acknowledge the duty to disclose in-part applications, material inform PCT international filing date of the	mation which became a	vallable between the filing	defined in 37 CFI g date of the prior	R 1.56, including for continuation- application and the national or	
I hereby claim foreign priority ben or plant breeder's rights certificat than the United States of Americ patent, inventor's or plant breede application on which priority is clai	a, listed below and har r's rights certificate(s), c	ve also identified below,	by checking the	box, any foreign application for	
Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES NO	
Additional foreign application	numbers are listed on a	supplemental priority dat	ta sheet PTO/SB/	02B attached hereto:	

[Page 1 of 2]

PTO/SB/01 (03-01)

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DECLARATION — Utility or Design Patent Application

Filtect all correspondence to: IN	er Numb Ode Lab		70	OR C	orrespondence add	ress below
Name						
Address						
City			State)	ZIP	
Country	Tel	ephone		<u>.</u>	Fax	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.						
NAME OF SOLE OR FIRST INVENTOR: A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any]) KAHN KAHN Family Name or Surname						
Inventor's Signature					Date	
BOULDER		CC				USA
Residence: City 3980 GREENBRIA	R BC	State DULEVART		Country	Citizenship	
Mailing Address						
BOULDER		CO		80303		JSA
NAME OF SECOND INVENTOR:		A netition has	been	zip filed for this unsi	Country	
Given Name CAROL A. (first and middle [if any])				Name BROVE		
Inventor's Signature					Date	
MENLO PARK Residence: City	- 1	CA State	Co	USA	Citizenship	USA
303 CONCORD DI	RIVE					
MENLO PARK		CA State	ZIP	94025	Country	JSA
Additional inventors are being named on the _	1_supp	olemental Additiona	al Inver	ntor(s) sheet(s) PTO/S	SB/02A attached her	reto.

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ADDITIONAL INVENTOR/S) Please type a plus sign (+) inside this box

DECLARATION

Supplemental Sheet Page _1_ of _1_

Name of Additional Joint Inventor, if any:				his unsigned inventor			
Given Name (first and middle [if a	Given Name (first and middle [if any])			Fa	Family Name or Surname		
KELLY A.			ì		KI	NG	DON
Inventor's X Lelly a XV	ng	da		Date 12-13-01		Date 12-13-01 USA	
Residence: City SAN RAFAEL	St	C.	A	Country			USA Citizenship
Mailing Address 4 MOUNT DIABL	O C	IRCLE					
Mailing Address							
city SAN RAFAEL	St	ate C.	A	ZIP 9490)3 c	ountr	usa
Name of Additional Joint Inventor, if a	any:			A petition has b	een filed	for thi	s unsigned inventor
Given Name (first and middle [if an	y])			Fai	mily Name	e or S	urname
Inventor's Signature							Date
Residence: City	St	ate		Country			Citizenship
Mailing Address							
Mailing Address							
City	St	ate		ZIP		Cour	itry
Name of Additional Joint Inventor, if any:							
Given Name (first and middle [if any])		Family Name or Surname					
Inventor's Signature Date			Date				
Residence: City State		Country Citizenship					
Mailing Address							
Mailing Address							
City	State	•		ZIP		Cou	ntry

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FEB 1 1 2002 U	PTO/SB/81 (02-01) Approved for use through 10/31/2002. OMB 0651-0035 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE pond to a collection of information unless it display a valid OMB control number.
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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	09/974,781
Filing Date	October 10, 2001
First Named Inventor	Michael G. Kahn
Title	CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY
Group Art Unit	2166
Examiner Name	Unknown
Attorney Docket Number	FSTK 1004-1US

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	r agent(s) to prosecute the application id		
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Firm or Individual Name	HAYNES BEFFEL & WOLFELD LLP		
Address	P.O.	. Box 366	
Address			
City		State CA Zip 94019	
Country	(470) -12 02 10	ates of America	
Telephone	(650) 712-0340 F	_{ax} (650) 712-0263	
I am the:			
✓ Applicant/Inventor	or.		
Assignee of record of the entire interest. See 37 CFR 3.71.			
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).			
SIGNATURE of Applicant or Assignee of Record			
Name MICHAEL G. KAHN			
Signature X Muckiel H. John			
Date X 19 December 2001			
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple			
forms if more than one signature i	1 1000	<u> </u>	
	ms are submitted.		

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	FEB 1 1 2002 (S)
POWER OF	ATTORNEY OR

Application Number	09/974,781
Filing Date	October 10, 2001
First Named Inventor	Michael G. Kahn
Title	CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY
Group Art Unit	2166
Examiner Name	Unknown
Attorney Docket Number	FSTK 1004-1US

I hereby appoint:			
OR	Customer Number 22,470	N. Label Jight 70 PATENT & TRADEMARK OFFICE	
Practitioner(s) na			
	Name	Registration Number	
as my/our attorney(s) or business in the United S	agent(s) to prosecute the application ide States Patent and Trademark Office conr	entified above, and to transact all nected therewith.	
	espondence address for the above-identi	fied application to:	
	ned Customer Number.	Place Customer	
OR ☐ Practitioners at Cus	stomer Number	Number Bar Code	
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Firm <i>or</i> Individual Name	HAYNES BEFFEL & WOLFELD LLP		
Address	P.O.	Box 366	
Address		2.010	
City		State CA Zip 94019	
Country		tes of America (650) 712-0263	
Telephone	(650) 712-0340 F	Fax (650) /12-0263	
I am the: Applicant/Inventor.			
Applicant/Inventor.			
Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).			
SIGNATURE of Applicant or Assignee of Record			
CAROL A. BROVERMAN			
Name Signature X Give A. Brov			
V 1 (24-3			
Date NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple			
forms if more than one signature is required, see below*.			
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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	09/974,781
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Title	CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY
Group Art Unit	2166
Examiner Name	Unknown
Attorney Docket Number	FSTK 1004-1US

I hereby appoint:			
 : :	Customer Number 22,470		
OR ☐ Practitioner(s) na	med helow.	PATENT & TRADEMARK OFFICE	
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as my/our attorney(s) or	agent(s) to prosecute the application ide States Patent and Trademark Office conr	entified above, and to transact all	
	espondence address for the above-identi		
	ed Customer Number.		
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Practitioners at Cus OR	stomer Number	Label here	
Firm or Individual Name	HAYNES BEFFE	L & WOLFELD LLP	
Address	P.O.	Box 366	
Address		21010	
City		State CA Zip 94019	
Country		tes of America (650) 712-0263	
Telephone	(630) /12-0340 F	Fax (650) 712-0263	
I am the: ✓ Applicant/Invent	or.		
Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).			
SIGNATURE of Applicant or Assignee of Record			
Name KELLY A. KINGDON			
Signature X Hell a Kingdon			
Date $\mathbf{X} / 2 - 13 - \emptyset 1$			
NOTE: Signatures of all the inver	tions or assignees of record of the entire interest o	r their representative(s) are required. Submit multiple	
forms if more than one signature *Total of One for	rns are submitted.		

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100	Application Number	09/974,781
FEB 1 1 2002	Filing Date	October 10, 2001
	First Named Inventor	Michael G. Kahn
POWER OF ATTORNEY OR AUTHORIZATION OF AGENT	Title	CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY
AUTHORIZĂŤIŒÑºŎF AGENT	Group Art Unit	2166
***	Examiner Name	Unknown
	Attorney Docket Number	FSTK 1004-1US

I hereby appoint:			
✓ Practitioners at 0	Customer Number 22,470		
OR		Lab 2 2-4 -7 ()	
Practitioner(s) na	med below:	PATENT & TRADEMARK OFFICE	
	Name	Registration Number	
as my/our attorney(s) o	r agent(s) to prosecute the application ide	entified above, and to transact all	
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	espondence address for the above-identit	fied application to:	
	ned Customer Number.		
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Firm or	TIANDEC DEDEC	I O WOLFELD LID	
Individual Name	Individual Name HATNES BEFFEL & WOLFELD LLP		
Address	P.O.	Box 366	
Address			
City	<u> </u>	State CA Zip 94019	
Country	United States of America		
Telephone	(650) 712-0340 Fax (650) 712-0263		
I am the:			
Applicant/Invent	or.		
Assistance of record of the antire interest. See 27 CED 2.71			
Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).			
SIGNATURE of Applicant or Assignee of Record			
MICHAEL GARAIN, VICE PRESIDENT			
Name Name			
Signature X Muchael & Tefan			
Date X 19 Decomber 2001			
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
	rms are submitted.		